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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,904	01/29/2001	Lorin R. Debonte	07148-063003 / A15-505.35	7898

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EXAMINER	
MCELWAIN, ELIZABETH F	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/771,904	Applicant(s) DEBONTE ET AL.	
	Examiner Elizabeth F. McElwain	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-14,16-19,28-30,35-42 and 44-46* is/are pending in the application.

4a) Of the above claim(s) ~~*1-9,11-14,16-19,28-30,35-42 and 44-46*~~ 4 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims, 1-3 in Paper No. 17 is acknowledged. The traversal is on the ground(s) that Group I should also include claims 7-9, 11, 16-19 and 35-40 given that the claims all relate to delta-12 desaturases and there would be no undue burden of search. This is not found persuasive because the claims are drawn to distinct sequences having different mutant forms, which would each require a separate search and examine. Therefore, there would be an undue burden of search and examination to rejoin these claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-9, 11-14, 16-19, 28-30, 35-42 and 44-46 are withdrawn from consideration as drawn to non-elected inventions.

The amendment filed June 13, 2003 has been entered.

Claims 2, 5, 17, 39, 42, 44, 45, and 46 have been newly amended.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are indefinite in that it is unclear what would distinguish a nucleic acid sequence from Brassicaceae or Helianthus from nucleic acid sequences from other genera or species. The specification fails to define or clarify how nucleic acids from these species would differ structurally from nucleic acids from other species, such that they could be distinguished on that basis.

Claims 1-3 are further indefinite in the recitation of "wherein said at least one mutation renders the product of said desaturase gene non-functional", because it is unclear what the product of a nucleic acid sequence that may be as small as 10 nucleotides and can have an unlimited number of mutations would be. It is also unclear what functional activity said product would have.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to an isolated nucleic acid fragment comprising at

least about 10 nucleotides from a Brassicaceae or Helianthus delta-12 fatty acid desaturase gene having at least one mutation in the region of the gene encoding a His-Xaa-Xaa-Xaa-His motif and which renders the gene non-functional. However, it is unclear what the structural characteristics or the function would be of a nucleic acid sequence that may be as small as 10 nucleotides and can have an unlimited number of mutations of a sequence that codes for a His-Xaa-Xaa-Xaa-His motif. It is further unclear how this mutated sequence would render said desaturase gene non-functional.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sequencing Primers (BRL Catalog and Reference Guide, 1989, page 61).

The claims are drawn to an isolated nucleic acid fragment comprising at least about 10 nucleotides from a Brassicaceae or Helianthus delta-12 fatty acid desaturase gene having at least one mutation in the region of the gene encoding a His-Xaa-Xaa-Xaa-His motif and which renders the gene non-functional.

The BRL Catalog at page 61 teaches sequencing primers of at least 10 nucleotides, which would be the same as a sequence of at least 10 nucleotides that codes for a His-Xaa-Xaa-Xaa-His motif that has an unspecified number of mutations. And the species and gene from which the sequence that is mutated is derived would not distinguish it from a nucleic acid having the same nucleotide sequence.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-3 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lightner et al (U.S. Patent 6,372,965, cited in IDS).

The claims are drawn to an isolated nucleic acid fragment comprising at least about 10 nucleotides from a Brassicaceae or Helianthus delta-12 fatty acid desaturase gene having at least one mutation in the region of the gene encoding a His-Xaa-Xaa-Xaa-His motif and which renders the gene non-functional.

Lightner et al (columns 13-14) teach a cloned nucleic acid from a Brassicaceae comprising a disrupted gene for delta-12 desaturation. The sequence taught by

Lightner et al is at least 10 nucleotides long and has at least one mutation resulting in disrupted function of the encoded desaturase. Lightner et al is silent with regard to the particular sequence of the mutant gene. However, it appears that the nucleic acid taught by Lightner et al is the same as the nucleic acid claimed, given the resultant lack of function of the desaturase gene. If the sequence taught by Lightner et al is not the same as the claimed sequence, then it appears to be so similar as to be an obvious variant. Thus the claimed invention would have been prima facie obvious in view of, if not anticipated by Lightner et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is 703-308-1794. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elizabeth F. McElwain
Primary Examiner
Art Unit 1638

EFM